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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,256	CHODOSH ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *1,2,5-38,41,45 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-4, 39-40, 42-44 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Sequence

DETAILED ACTION

Election/Restrictions

The Election filed on October 13, 2004 in response to the Restriction Requirement of July 15, 2004 is acknowledged and has been entered. Applicant has elected without traverse Group I, Claims 3-4, 39-40, 42-44 and 46, drawn to an isolated nucleotide comprising the nucleotide sequence set forth in SEQ ID NO: 1.

Claims 1-47 are currently pending

Claims 1-2, 5-38, 41, 45 and 47 are withdrawn as being drawn to a non-elected invention.

Claims 3-4, 39-40, 42-44 and 46 are currently under consideration.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. The specification, on page 51, line 1, discloses the following embedded hyperlink: http://www.informatics.jax.org/. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claim 3 is objected to because of the following informalities: Claim 3 refers to an isolated nucleotide sequence encoding the kinase of claim 1, which is a non-elected invention. Appropriate correction is required.

Note: Claim 3 will be interpreted as drawn to an isolated nucleic acid encoding a Hunk kinase.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 39-40, 42-44 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 39-40, 42-44 and 46 are rejected as vague and indefinite for reciting the term Hunk in association with being encoded by an isolated nucleic acid as the sole means of identifying the claimed molecule. The use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. The rejection can be obviated by amending the claims to specifically and uniquely identify Hunk, for example, by SEQ ID NO. and function of Hunk.

Claims 42-44 are further rejected as being indefinite because it recites the phrase "Hunk activity" in claim 42. "Hunk activity" is not defined by the claim. Although the specification considers how to assess the term "activity" (page 28, lines 15-17), it does not provide a limited definition for ascertaining the requisite degree of characterization sought in the claims and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and would not be able to determine the metes and bounds of the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 39-40, 42-44 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of nucleic acids comprised on the

nucleotide sequence set forth in SEQ ID NO: 1 or any mutant, derivative, homolog or fragment thereof. However, the written description in this case only sets forth a Hunk gene consisting of the nucleotide sequence set forth in SEQ ID NO: 1 and a nucleotide sequence of human HUNK set forth in SEQ ID NO: 18.

The specification teaches (page 8, 2nd full paragraph) that specific nucleic acids of the invention include, but are not limited to, molecules that are complementary to all or part of the Hunk or HUNK, and to mutants, derivatives, homologs, or fragments thereof which encode a cell having Hunk activity. With regards to a complementary sequence, the specification discloses (page 8, 2nd full paragraph) that a complementary sequence comprises antisense activity at a level sufficient to regulate, control, or modulate Hunk activity in a target cell expressing the kinase. With regards to homolog or homologous, the specification teaches (page 18 bridging 19, lines 26+) that homologous includes, but is not limited to, subunit sequence similarity between two polymeric molecules, e.g. between two nucleic acid molecules, wherein the homology between two sequences is a direct function of the number of matching or homologous position, e.g. if half (e.g., five positions in a polymer ten subunits in length) of the positions in two compound sequences are homologous then the two sequences are 50% homologous. However, the written description only sets forth murine Hunk gene (SEQ ID NO: 1) and the human HUNK homolog (SEQ ID NO: 18); and therefore, is not commensurate with the full scope of any and all mutants, derivatives, homologs, or fragments thereof of the nucleotide sequence set forth in SEQ ID NO: 1. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of nucleotide sequences that encompass the genus of nucleic acids nor does it provide a description of structural features that are common to the nucleic acids. Since

the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of one species of SEQ ID NO: 1 is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of nucleic acids, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only a Hunk gene consisting of the nucleotide sequence set forth in SEQ ID NO: 1 and a nucleotide sequence of human HUNK homolog set forth as SEQ ID NO: 18, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 3-4, 39-40, and 42-44 are rejected under 35 U.S.C. 102(a) as being anticipated by Gardner *et al.* (Genomics 2000, 64, 46-59).

In the instant case, the claims are drawn to an isolated nucleotide sequence comprising the nucleotide sequence set forth in SEQ ID NO: 1, which encodes a protein kinase referred to as "Hunk", and also to a recombinant cell, mammalian cell, and vector comprising the isolated nucleic acid of SEQ ID NO: 1. The claims are further drawn to an isolated nucleic acid sequence comprising a sequence complementary to all or part of the nucleic acid sequence set forth in SEQ ID NO: 1 and to an isolated nucleic acid of SEQ ID NO: 1 comprising antisense activity.

Gardner et al. teach (page 49, Fig. 1, see attached Accession No. AF167987) the isolation of a nucleic acid which appears to be 100% identical to the claimed nucleotide sequence set forth in SEQ ID NO: 1. The reference also teaches (Abstract) that the isolated cDNA (*i.e., complementary DNA*) encodes a 714 amino acid protein referred to as "Hunk" (Abstract). Gardner *et al.* further teach (page 47, Material and Methods) a vector (Uni-Zap), recombinant cell, and mammalian cell comprising the nucleic acid. Furthermore, the reference teaches the generation of antisense and sense probes containing sequences corresponding to nucleotides 276 to 793 of Hunk.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 39, and 42-44 are further rejected under 35 U.S.C. 102(b) as being anticipated by NCBI database for nucleotides (Accession Number: AF055919, 4/28/1999).

In the instant case, the claims are drawn to an isolated nucleotide which encodes a kinase and also to a cell comprising the isolated nucleic acid of SEQ ID NO: 1. The claims are further drawn to an isolated nucleic acid sequence comprising a sequence complementary to all or part of the nucleic acid sequence set forth in SEQ ID NO: 1 and to an isolated nucleic acid of SEQ ID NO: 1 comprising antisense activity.

NCBI database for nucleotides discloses Accession Number: AF055919 which appears to be 98.8% identical to the claimed nucleotide sequence set forth in SEQ ID NO: 1 (see attached). The reference further teaches (located under source, Page 2) a cell line comprising the nucleotide sequence. Furthermore, the reference teaches a nucleic acid comprising antisense activity. Although the reference does not specifically teach a complementary nucleic acid, DNA itself is made up of two complementary strands of nucleotides as evidenced by Alberts *et al.* (Molecular Biology of the

Cell, see attached). Thus, it does not appear that the claimed language or limitations results in a manipulative difference in the nucleic acids when compared to the prior art disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 40 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accession No. AF167987 as applied to claim 3, 39, and 42-44 above, and further in view of Naylor, L.H. (Biochemical Pharmacology 1999, 58: 749-757).

In the instant case, the claims are drawn to an isolated nucleotide sequence which encodes a protein kinase, further comprising a reporter gene operably fused thereto. The claims are further drawn to a vector comprising the isolated nucleotide sequence.

Accession No. AF167987 teach a nucleic acid which appears to be 98.8% identical to the claimed nucleotide sequence set forth in SEQ ID NO: 1. Accession No. AF167987 does not teach the nucleic acid further comprising a reporter gene or a vector.

Naylor, J.H. teach (abstract) that reporter gene technology is widely used to monitor the cellular events associated with signal transduction and gene expression. The reference further discloses (abstract) that the advantage of these assays is their high sensitivity, reliability, convenience, and adaptability to large-scale measurements. Furthermore, the reference teaches (page 752, 1st column, 3rd paragraph) that gene encoding therapeutic proteins for the treatment of disease have been introduced into mammalian cells using a variety of techniques including viral ad retroviral vectors.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to fuse a reporter gene to a nucleic acid. As evidenced by Naylor, it is well known in the art that reporter gene technology is used to monitor cellular events, such as expression and allows for high sensitivity, reliability, convenience, and adaptability to large-scale measurements.

Thus, one of ordinary skill in the art would have a reasonable expectation that by combining a reporter gene with the nucleotide sequence taught by Accession No. AF167987, one would achieve a method of measuring gene expression with high sensitivity, reliability, and convenience. In addition, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a vector comprising an isolated nucleic acid. As evidenced by Naylor, it is well known in the art that genes encoding therapeutic proteins are introduced into mammalian cells using either viral or retroviral vectors. Thus, one of ordinary skill in the art would have a reasonable expectation that by making a vector comprising the nucleotide sequence taught by Accession No: AF167987, one would achieve a delivery agent that can be used to treat a disease.

Therefore, NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

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PRIMARY EXAMINER